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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,075

03/30/2004

Yoshinori Sekiguchi

Q74855

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23373 7590 06/05/2008  
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EXAMINER

JAISLE, CECILIA M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

06/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/812,075	<b>Applicant(s)</b> YOSHINORI SEKIGUCHI, ET AL.	
	<b>Examiner</b> CECILIA M. JAISLE	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008 and 08 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,52-67,69-96,99-101,103-106 and 112 is/are pending in the application.
- 4a) Of the above claim(s) 52-56,59-62,65-67,69-71,73,74 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,75-77,79,82-85,88-90,93,94,100,103 and 112 is/are rejected.
- 7) ☒ Claim(s) 57,58,63,64,72,78,80,81,86,87,91,92,95,96,99 and 101 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED OFFICE ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on April 8 and May 8, 2008 have been entered.

### **Election/Restriction**

Applicant's election of Group III, drawn to compounds of formula I wherein Q is formula IV (pyrimidine), and pharmaceutical compositions thereof, classified in classes 514 and 544, various subclasses depending on substituents, in the reply filed on Oct. 23, 2006 is acknowledged. Applicant's further election of the species of Example 3398, 3-chloro-N-[cis-4-(4-dimethylamino-5-methyl-pyrimidin-2-ylamino)-cyclohexyl]-4-fluorobenzamide methanesulfonic acid, in the further reply filed on Mar. 13, 2007 is also acknowledged. Claims 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 112 read on the elected species, and these claims are under examination only to the extent that they are patentably indistinct from the elected species. Claims 52-56, 59-62, 65-67, 69-71, 73, 74 and 104-106 are withdrawn as non-elected. It is noted that Applicants' request for

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rejoinder of method claims 104-106 is held in abeyance pending determination of the allowability of the compound and compositions claims.

### ***Rejections Under 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

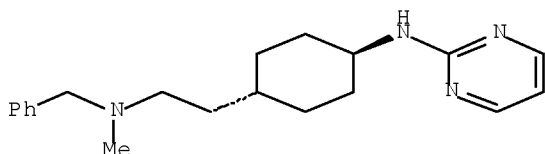
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes common ownership of the subject matter of the various claims at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to identify the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made so that the examiner may consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

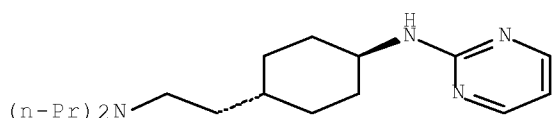
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining differences between the prior art and claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 75-77, 79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected under 35 U.S.C. 103(a) as being obvious over Wustrow, describing RN 204245-70-5, 2-Pyrimidinamine, N-[4-[2-[methyl(phenylmethyl)amino]ethyl]cyclohexyl]-, trans-,

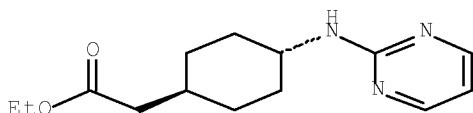


,  
RN 204245-89-6, 2-Pyrimidinamine, N-[4-[2-(dipropylamino)ethyl]cyclohexyl]-, trans-,



, and

RN 189153-07-9, Cyclohexaneacetic acid, 4-(2-pyrimidinylamino)-, ethyl ester, trans-,



. Each of these compounds are lower alkyl

homologs of the presently claimed compounds, where the present claims require that the pyrimidine ring is substituted by R2, which may be lower alkyl.

It would have been obvious to one of ordinary skill in the art at the time the present invention was made to modify the Wustrow compounds to prepare the alkyl homologs and position isomers thereof. One of ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous and isomeric compounds are expected to possess similar properties to the Wustrow compounds as having high affinity for serotonin and dopamine receptors. It

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has been held that compounds that are structurally homologous and isomeric to prior art compounds are *prima facie* obvious, absent a showing of unexpected results.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

*In re Payne*, 203 USPQ 245, 254 (CCPA 1979). *In re Papesch*, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed in MPEP § 2144) for an extensive case law review of obviousness based on close structural chemical compound similarity. See MPEP § 2144.08, ¶ II.A.4(c). Compounds which are homologs (compounds differing regularly by the successive addition or subtraction of the same chemical group, e.g., by -CH<sub>3</sub> or lower alkyl groups), as here, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 195 USPQ 426 (CCPA 1977).

***Comments on the April 8, 2008 Amendment and Kanuma Declaration***

Compound 1 of the Kanuma Declaration is not the compound of the prior art Wustrow reference. The Wustrow compound has a methylene between the phenyl ring and the amino. Compound 1 of the Kanuma Declaration has an ethylene between the phenyl ring and the amino.

The Kanuma Declaration presents tests with only the two prior art compounds (although Compound 1 is not the actual prior art Wustrow compounds, as discussed above), but does not present simultaneous tests with the closest compound of the invention: Example 19. The information provided in the specification is not sufficient to

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compare with the purported two prior art compounds. The Declaration provided with the filing of this application only declares that the inventors are the first and true inventors, not that everything in the specification is true. The Kanuma Declaration testing must be repeated with the correct closest prior art compounds compared directly to the closest compounds of the present claims.

### ***Objected Claims***

Claims 57, 58, 63, 64, 68, 72, 78, 80, 81, 86, 87, 91, 92, 95, 96, 99 and 101 are objected to as dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims.

### ***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J. D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624

Cecilia M. Jaisle, J. D.  
5/27/2008